



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,924	09/13/2000	James E. Dahlberg	FORS-04623	8263

23535 7590 10/21/2003
MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER

SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 10/21/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant N .

09/660,924

Applicant(s)

DAHLBERG ET AL.

Examiner

William Sandals

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 112-117 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 112-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Claims

Claims 112-117 are pending.

The amendments to claims 112 and 116 in Paper No. 20, filed June 18, 2003 have overcome the rejections of the claims under 35 USC 112, second paragraph, and the rejections are withdrawn.

Claims 112-117 stand rejected under 35 USC 102(e) over US 5,210,015 (Gelfand et al.).

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 112-117 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,210,015 (Gelfand et al.).

Gelfand et al. teach at the abstract and at column 2, a method of modifying or detecting a polynucleotide by providing a target nucleic acid (this corresponds to the instant claimed polynucleotide) which hybridizes to a first oligonucleotide (this corresponds to the instant claimed first oligonucleotide). The 3' portion of the first oligonucleotide hybridizes to the 5' portion of the target nucleic acid. A 5' nuclease cleaves the unhybridized 5' portion of the target nucleic acid. The 3' portion of the target nucleic acid hybridizes to the first oligonucleotide. The 5' portion of the target nucleic acid hybridizes to a labeled oligonucleotide (this corresponds to the second oligonucleotide of instant claim 113). The target nucleic acid may be from a virus (see Gelfand et al. at column 7, last paragraph) as recited in claim 115. The hybridization sites are contiguous, and the labeled oligonucleotide has a label (see column 2, lines 27-39) as recited in claims 116 and 117. The cleaved fragments are detected by the presence of the label as recited in claim 114.

Arguments presented in Paper No. 20, pages 4-5, assert that the instant claims were copied from US Pat Nos. 6,110,677 and 6,121,001. It is asserted that the Gelfand reference was cited in US Pat Nos. 6,110,677 and 6,121,001, and the claims in US Pat Nos. 6,110,677 and 6,121,001 were allowed and issued in view of Gelfand. It is asserted that Gelfand et al. does not teach a method employing isothermal conditions.

It is also asserted that Gelfand et al. does not teach oligonucleotides having a 5' portion which does not hybridize to the target polynucleotide.

Gelfand et al. has been carefully reviewed to assure that the above rejection is accurate and correct.

At column 21, lines 34-43, Gelfand et al. teach that the reaction was conducted at 70° C. which is at or near the T_m of the primers used in the hybridization/nuclease assay. The T_m is a known point at which 50% of the primers are hybridized, and 50% of the primers are unhybridized. This is also known as the "isothermal conditions" of the reaction (see Gelfand et al. at column 5, lines 19-23). Thus, Gelfand et al. did teach isothermal conditions.

At column 13, line 59 – column 14, line 31, Gelfand et al. teach that the probe (identified as BW33 in Gelfand et al., see column 14) is designed to have a region which hybridizes (taught as a complementary sequence) and a region which does not hybridize (taught as a non complementary 5' tail region). At column 20, line 60 – column 22, line 17, Gelfand et al. teach that the probe (BW33) is used in the method to test for 5' nuclease activity. The probe is cleaved, releasing the 5' end. Thus, Gelfand et al. teach that the oligonucleotide has a 5' portion which does not hybridize to the target polynucleotide. Therefore, the arguments are not found persuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Sandals whose telephone number is (703) 305-1982. The examiner can normally be reached on Monday to Thursday, 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

William Sandals


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600


John J. Doll, Director
Technology Center 1600